



BILLING CODE: 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2013-0042]

Dow AgroSciences LLC; Determination of Nonregulated Status of Herbicide Resistant Corn and Soybeans

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination that three varieties of herbicide resistant corn and soybeans produced by Dow AgroSciences LLC are no longer considered regulated articles under our regulations governing the introduction of certain genetically engineered organisms. Our determination is based on our evaluation of data submitted by the Dow AgroSciences LLC in its three petitions for a determination of nonregulated status, our analysis of publically available scientific data, and comments received from the public on the petition for nonregulated status and its associated environmental impact statement and plant pest risk assessments. This notice also announces the availability of our written determination and record of decision.

DATES: EFFECTIVE DATE: [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may read the documents referenced in this notice and any comments we received in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room

hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming. Those documents are also available on the Internet at

http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml under APHIS Petition Numbers 09-233-01p, 09-349-01p, and 11-234-01p and are posted with the comments we received on the Regulations.gov Web site at

<http://www.regulations.gov/#!docketDetail;D=APHIS-2013-0042>.

FOR FURTHER INFORMATION CONTACT: Dr. John Turner, Director, Environmental Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 851-3954, email: john.t.turner@aphis.usda.gov. To obtain copies of the documents referenced in this notice, contact Ms. Cindy Eck at (301) 851-3892, email: cynthia.a.eck@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

The regulations in 7 CFR part 340, “Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests,” regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered (GE) organisms and products are considered “regulated articles.”

The regulations in § 340.6(a) provide that any person may submit a petition to APHIS seeking a determination that an article should not be regulated under 7 CFR part 340.

Paragraphs (b) and (c) of § 340.6 describe the form that a petition for a determination of nonregulated status must take and the information that must be included in the petition.

APHIS received three petitions (referred to below as “the petitions”) from Dow AgroSciences LLC seeking determinations of nonregulated status for corn and soybean cultivars genetically engineered to be resistant to herbicides. The first petition, APHIS Petition Number 09-233-01p, seeks a determination of nonregulated status for corn (Zea mays) designated as event DAS-40278-9, which has been genetically engineered for increased resistance to certain broadleaf herbicides in the phenoxy auxin group (particularly the herbicide 2,4-D) and resistance to grass herbicides in the aryloxyphenoxypropionate (AOPP) acetyl coenzyme A carboxylase (ACCase) inhibitor group (i.e., “fop” herbicides, such as quizalofop-p-ethyl). The second petition, APHIS Petition Number 09-349-01p, seeks a determination of nonregulated status for soybean (Glycine max) designated as event DAS-68416-4, which has been genetically engineered for resistance to certain broadleaf herbicides in the phenoxy auxin growth regulator group (particularly the herbicide 2,4-D) and the nonselective herbicide glufosinate. The third petition, APHIS Petition Number 11-234-01p, seeks a determination of nonregulated status for soybean designated as event DAS-44406-6, which has been genetically engineered for resistance to certain broadleaf herbicides in the auxin growth regulator group (particularly the herbicide 2,4-D) and the nonselective herbicides glyphosate and glufosinate. The petitions state that these articles are unlikely to pose a plant pest risk and, therefore, should not be regulated articles under APHIS' regulations in 7 CFR part 340.

Notices were published¹ in the Federal Register for each petition advising the public that APHIS had received the petition and was seeking public comments on the petition. The notices

¹ Docket No. APHIS-2010-0103 published on December 27, 2011, 76 FR 80872-80873; Docket No. APHIS-2012-0019 published on July 13, 2012, 77 FR 41367-41368; and Docket No. APHIS-2012-0032 published on July 13, 2012, 77 FR 41361-41362. The Federal Register notices for the petitions and supporting and related materials, including public comments, are available at <http://www.regulations.gov/#!docketDetail;D=APHIS-2010-0103>; <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0019>; and <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0032>.

for the first two petitions (DAS-40278-9 corn and DAS-68416-4 soybean) additionally sought comment on our plant pest risk assessment (PPRA) and our draft environmental assessment (EA) for each petition.

Following review of public comments, we published another notice² in the Federal Register on May 16, 2013 (78 FR 28798-28800, Docket No. APHIS-2013-0042), advising the public of our intent to prepare an environmental impact statement (EIS) for the potential determination of nonregulated status requested by the petitions. APHIS decided to prepare an EIS in order to perform a comprehensive environmental analysis of the potential environmental impacts that may occur as a result of granting a determination of nonregulated status for these three events.

National Environmental Policy Act and Record of Decision

To provide the public with documentation of APHIS' review and analysis of the potential environmental impacts associated with a determination of nonregulated status of DAS-40278-9 corn, DAS-68416-4 soybean, and DAS-44406-6 soybean, an EIS has been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 et seq.); (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508); (3) USDA regulations implementing NEPA (7 CFR part 1b); and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

A notice of availability regarding the draft EIS prepared by APHIS was published by the Environmental Protection Agency (EPA) in the Federal Register on January 10, 2014 (79 FR

² To view the notice the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2013-0042>.

1861-1862, Docket No. ER-FRL-9012-9). Along with the draft EIS,³ APHIS also made available the PPRA for the third petition, DAS-44406-6 soybean, along with the PPRAs for the first two petitions (DAS-40278-9 corn and DAS-68416-4 soybean). APHIS reviewed and evaluated all of the public comments received on the draft EIS and prepared formal responses to them as part of the final EIS.

A notice of availability regarding the final EIS prepared by APHIS was published by EPA in the Federal Register on August 8, 2014 (79 FR 46439, Docket No. ER-FRL-9016-3). The NEPA implementing regulations in 40 CFR 1506.10 require a minimum 30-day review period between the time the notice of availability of a final EIS is published and the time an agency makes a decision on an action covered by the EIS. APHIS has reviewed and evaluated the comments received during the 30-day review period and has concluded that it has fully and appropriately analyzed the relevant environmental issues covered by the final EIS and those comments. Based on our final EIS, the response to public comments, and other pertinent scientific data, APHIS has prepared a record of decision for the final EIS.

Determination of Nonregulated Status

Based on APHIS' analysis of field and laboratory data submitted by Dow AgroSciences LLC, references provided in the petitions, peer-reviewed publications, information analyzed in the EIS, the PPRAs, comments provided by the public, and APHIS' evaluation of and response to those comments, APHIS has determined that DAS-40278-9 corn, DAS-68416-4 soybean, and DAS-44406-6 soybean are unlikely to pose a plant pest risk. Accordingly, the petitions requesting a determination of nonregulated status are approved and DAS-40278-9 corn, DAS-68416-4 soybean, and DAS-44406-6 soybean are no longer subject to our regulations governing

³ To view the draft EIS, final EIS, supporting documents, and the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2013-0042>.

the introduction of certain genetically engineered organisms and to the plant pest provisions of the Plant Protection Act.

Copies of the three signed determination documents for nonregulated status and the signed record of decision for the EIS, as well as copies the final EIS and the three PPRA's are available as indicated in the ADDRESSES and FOR FURTHER INFORMATION CONTACT sections of this notice.

Authority: 7 U.S.C. 7701-7772 and 7781-7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 15th day of September 2014.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2014-22409 Filed 09/19/2014 at 8:45 am; Publication Date: 09/22/2014]